Notice of Allowability	Application No.	Applicant(s)	
	10/695,846	PHILPOTT ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *30-32,60-71,76-79 and 84-110*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

In the response filed on 09 March 2007, claims 1-19, 54-59, 72-75, 80-83, and 111-116 have been cancelled. Claims 20-53, 60-71, 76-79 and 84-110 are pending.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Deborah Lu on 08 June 2007.

Please cancel claims 20-29 and 33-53.

Claims 30-32, 60-71, 76-79 and 84-110 are allowable.

The application has been amended as follows:

30. A diagnostic method of determining viral receptor tropism comprising:

(a) obtaining a population of acquired immunodeficiency virus from a patient;

(b) determining CXCR4 coreceptor use;

(c) determining CCR5 coreceptor use; and

(d) determining the ratio of acquired immunodeficiency virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor.

31. A diagnostic method of determining viral receptor tropism comprising:

(a) obtaining a population of acquired immunodeficiency virus from a patient;

(b) determining CXCR4 coreceptor use;

(c) determining CCR5 coreceptor use; and

(d) determining the ratio of acquired immunodeficiency virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor before initiating antiretroviral therapy to determine a suitable antiretroviral treatment regimen.

32. A diagnostic method of determining viral receptor tropism comprising:

(a) obtaining a population of acquired immunodeficiency virus from a patient;

(b) determining CXCR4 coreceptor use;

(c) determining CCR5 coreceptor use; and

(d) determining the ratio of acquired immunodeficiency virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor after initiating antiretroviral therapy.

60. A diagnostic method of determining CXCR4 and/or CCR5 coreceptor usage in a patient before initiating antiretroviral therapy, comprising:

(a) obtaining an acquired immunodeficiency virus from a patient;

(b) quantitating usage of the CXCR4 and/or CCR5 coreceptor in an acquired immunodeficiency virus primary isolate from a patient, whereby the CXCR4 and/or CCR5 coreceptor usage of the patient is used to determine a suitable antiretroviral treatment regimen.

63. The method according to claim 60, wherein the acquired immunodeficiency virus sample is obtained from peripheral blood of a patient.

64. The method according to claim 60, wherein the acquired immunodeficiency virus sample is obtained from genital secretions of a patient.

65. The method according to claim 60, wherein the acquired immunodeficiency virus sample is obtained from cerebrospinal fluid of a patient.

66. A diagnostic method of monitoring the efficacy of antiretroviral therapy in a patient comprising:

(a) obtaining acquired immunodeficiency virus samples from a patient before and after initiating antiretroviral therapy; and

(b) quantitating usage of the CXCR4 and/or CCR5 coreceptor in the samples, whereby a decrease of CXCR4 coreceptor use after initiating antiretroviral therapy indicates that the antiretroviral therapy is effective.

69. The method according to claim 66, wherein the acquired immunodeficiency virus sample is obtained from peripheral blood of a patient.

70. The method according to claim 66, wherein the acquired immunodeficiency virus sample is obtained from genital secretions of a patient.

71. The method according to claim 66, wherein the acquired immunodeficiency virus sample is obtained from cerebrospinal fluid of a patient.

76. A diagnostic method of determining a suitable antiretroviral treatment regimen before initiating antiretroviral therapy comprising:

(a) determining CXCR4 and CCR5 coreceptor use in an acquired immunodeficiency virus sample from a patient; and

(b) determining the ratio of acquired immunodeficiency virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor before initiating

antiretroviral therapy, whereby the ratio of CXCR4 to CCR5 coreceptor usage is used to determine a suitable antiretroviral treatment regimen.

77. The method according to claim 76, wherein the acquired immunodeficiency virus sample is obtained from peripheral blood of a patient.

78. The method according to claim 76, wherein the acquired immunodeficiency virus sample is obtained from genital secretions of a patient.

79. The method according to claim 76, wherein the acquired immunodeficiency virus sample is obtained from cerebrospinal fluid of a patient.

84. A diagnostic method of monitoring the efficacy of antiretroviral therapy in a patient comprising the steps of:

a) obtaining a first acquired immunodeficiency virus sample from a patient before the initiation of antiretroviral therapy;

b) assaying the first sample for CXCR4 and CCR5 coreceptor use;

c) determining in the first sample the ratio of virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor;

d) obtaining a second acquired immunodeficiency virus sample from said patient at a time subsequent to the initiation of antiretroviral therapy and subsequent to the time at which the first sample is obtained;

e) repeating steps b) through c) with the second sample;

f) determining whether there is a difference in the ratio of CXCR4 and CCR5 coreceptor usage between the first and second sample from said patient, whereby an increase in the ratio of CCR5 coreceptor usage, or a decrease in the ratio of CXCR4

coreceptor in the second sample as compared to the first sample, indicates that the antiretroviral therapy is effective.

86. The method according to claim 84, wherein the acquired immunodeficiency virus sample is obtained from peripheral blood of a patient.

87. The method according to claim 84, wherein the acquired immunodeficiency virus sample is obtained from genital secretions of a patient.

88. The method according to claim 84, wherein the acquired immunodeficiency virus sample is obtained from cerebrospinal fluid of a patient.

93. A diagnostic method of monitoring the efficacy of antiretroviral therapy in a patient comprising the steps of:

a) obtaining a first acquired immunodeficiency virus sample from a patient either before or after the initiation of antiretroviral therapy;

b) assaying the first sample for CXCR4 and CCR5 coreceptor use;

c) determining in the first sample the ratio of virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor;

d) obtaining a second acquired immunodeficiency virus sample from said patient at a time subsequent to the initiation of antiretroviral therapy and subsequent to the time at which the first sample is obtained;

e) repeating steps b) through c) with the second sample;

f) determining whether there is a difference in the ratio of CXCR4 and CCR5 coreceptor usage between the first and second sample, whereby a decrease in the ratio of CCR5 coreceptor usage, or an increase in the ratio of CXCR4 coreceptor in the

second sample as compared to the first sample, indicates that the antiretroviral therapy is not effective.

95. The method according to claim 93, wherein the acquired immunodeficiency virus sample is obtained from peripheral blood of a patient.

96. The method according to claim 93, wherein the acquired immunodeficiency virus sample is obtained from genital secretions of a patient.

97. The method according to claim 93, wherein the acquired immunodeficiency virus sample is obtained from cerebrospinal fluid of a patient.

102. A diagnostic method of monitoring the efficacy of antiretroviral therapy in a patient comprising the steps of:

a) obtaining a first acquired immunodeficiency virus sample from a patient either before or after the initiation of antiretroviral therapy;

b) assaying the first sample for CXCR4 or CCR5 coreceptor use;

c) determining in the first sample the ratio of virus using the CXCR4 coreceptor compared to virus using the CCR5 coreceptor;

d) obtaining a second acquired immunodeficiency virus sample from said patient at a time subsequent to the initiation of antiretroviral therapy and subsequent to the time at which the first sample is obtained;

e) repeating steps b) through c) with the second sample;

f) determining whether there is a difference in the ratio of CXCR4 and CCR5 coreceptor usage between the first and second sample, whereby the lack of a difference in the ratio of CCR5 coreceptor usage, or the lack of a difference in the ratio of CXCR4

coreceptor usage, between the first and second sample, indicates that the antiretroviral therapy is not effective.

104. The method according to claim 102, wherein the acquired immunodeficiency virus sample is obtained from peripheral blood of a patient.

105. The method according to claim 102, wherein the acquired immunodeficiency virus sample is obtained from genital secretions of a patient.

106. The method according to claim 102, wherein the acquired immunodeficiency virus sample is obtained from cerebrospinal fluid of a patient.

Claims 30-32, 60-71, 76-79 and 84-110 are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9:30 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Louise Humphrey, Ph.D.
Assistant Patent Examiner
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BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600